



Complete Summary

GUIDELINE TITLE

Diabetic retinopathy.

BIBLIOGRAPHIC SOURCE(S)

American Academy of Ophthalmology Retina/Vitreous Panel, Preferred Practice Patterns Committee. Diabetic retinopathy. San Francisco (CA): American Academy of Ophthalmology (AAO); 2008. 39 p. [162 references]

GUIDELINE STATUS

This is the current release of the guideline.

This guideline updates a previous version: American Academy of Ophthalmology Retina Panel, Preferred Practice Patterns Committee. Diabetic retinopathy. San Francisco (CA): American Academy of Ophthalmology (AAO); 2003. 33 p.

All Preferred Practice Patterns are reviewed by their parent panel annually or earlier if developments warrant and updated accordingly. To ensure that all Preferred Practice Patterns are current, each is valid for 5 years from the "approved by" date unless superseded by a revision.

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SCOPE

DISEASE/CONDITION(S)

Diabetic retinopathy

GUIDELINE CATEGORY

Diagnosis
Evaluation
Management
Prevention
Risk Assessment
Screening
Treatment

CLINICAL SPECIALTY

Endocrinology
Family Practice
Internal Medicine
Ophthalmology
Pediatrics

INTENDED USERS

Physicians

GUIDELINE OBJECTIVE(S)

To prevent, retard, or reverse visual loss, thereby maintaining or improving vision-related quality of life by addressing the following goals:

- Identify patients at risk of developing diabetic retinopathy
- Encourage involvement of the patient and primary care physician in the management of the patient's systemic disorder, with specific attention to control of blood sugar (hemoglobin A1c), blood pressure and serum lipids
- Encourage and provide lifelong evaluation of retinopathy progression
- Treat patients at risk for visual loss from diabetic retinopathy
- Minimize the side effects of treatment that might adversely affect the patient's vision and/or vision-related quality of life
- For patients with visual impairment from the disease, either provide visual rehabilitation services or refer the patient for such services

TARGET POPULATION

Patients with diabetes mellitus

INTERVENTIONS AND PRACTICES CONSIDERED

Diagnosis/Evaluation

1. Medical and ocular history
2. Comprehensive adult medical eye evaluation
3. Examination of peripheral retina and vitreous using slit-lamp biomicroscopy or indirect ophthalmoscopy with a contact lens
4. Examination for presence of macular edema, optic nerve head neovascularization, and other features that might lead to visual impairment
5. Eye examination schedule

6. Ancillary tests, including color fundus photography, optical coherence tomography, fluorescein angiography, ultrasonography

Management/Treatment

1. Panretinal photocoagulation (scatter) laser surgery
2. Focal and/or grid laser surgery
3. Fluorescein angiography
4. Follow-up care of patient
5. Referral if appropriate
6. Patient education

MAJOR OUTCOMES CONSIDERED

- Prevalence of retinopathy and vision-threatening retinopathy
- Visual function
- New cases of legal blindness
- Vision-related quality of life
- Quality-adjusted life years
- Cost-effectiveness
- Coordination of care management to achieve optimal glycemic control

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

In the process of revising this document, a detailed literature search of articles in the English language was conducted on the subject of diabetic retinopathy for the years 2002 to 2007.

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Weighting According to a Rating Scheme (Scheme Given)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Ratings of Strength of Evidence

Level I includes evidence obtained from at least one properly conducted, well-designed randomized, controlled trial. It could include meta-analyses of randomized controlled trials.

Level II includes evidence obtained from the following:

- Well-designed controlled trials without randomization
- Well-designed cohort or case-control analytic studies, preferably from more than one center
- Multiple-time series with or without the intervention

Level III includes evidence obtained from one of the following:

- Descriptive studies
- Case reports
- Reports of expert committees/organization (e.g., Preferred Practice Patterns [PPP] panel consensus with external peer review)

METHODS USED TO ANALYZE THE EVIDENCE

Systematic Review

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Not stated

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

The results of a literature search on the subject of diabetic retinopathy were reviewed by the Retina Panel and used to prepare the recommendations, which they rated in two ways. The panel first rated each recommendation according to its importance to the care process. This "importance to the care process" rating represents care that the panel thought would improve the quality of the patient's care in a meaningful way. The panel also rated each recommendation on the strength of the evidence in the available literature to support the recommendation made.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Ratings of Importance to Care Process

Level A, defined as most important

Level B, defined as moderately important

Level C, defined as relevant but not critical

COST ANALYSIS

Computer-simulation models have been designed to predict the medical and economic effects of applying accepted methods for controlling diabetic retinopathy

among patients with type 1 diabetes. In one study, recommendations for screening were taken from the Public Health Committee of the American Academy of Ophthalmology. Surgery recommendations and modeled treatment efficacy were drawn from the reports of the Diabetic Retinopathy Study and the Early Treatment Diabetic Retinopathy Study. Costs of screening and surgery were drawn from published Medicare reimbursement data.

The model predicted that over their lifetime, 72% of patients with type 1 diabetes will eventually develop proliferative diabetic retinopathy requiring panretinal photocoagulation and that 42% will develop macular edema. If treatments are delivered as recommended in the clinical trials, the model predicted a cost of \$966 per person-year of vision saved from proliferative diabetic retinopathy and \$1120 per person-year of central visual acuity saved from macular edema. These costs are less than the cost of a year of Social Security disability payments for those disabled by vision loss. In addition, if all type 1 patients received eye care at federal expense, the predicted savings exceed \$167.0 million and 79,236 person-years of sight. Therefore, treatment yields a substantial savings compared with the direct cost to society of the case of an untreated type 1 patient. The indirect costs, in lost productivity and human suffering, are even greater.

Another analysis, using the same computer model, predicted the cost-effectiveness of detecting and treating diabetic retinopathy from the insurers' perspective. Screening and treatment of eye disease in patients with diabetes costs, on average, \$3,190 per quality-adjusted life-year (QALY) saved. For patients with type 1 diabetes, it costs \$1,996 per QALY saved; for patients with type 2 diabetes who use insulin, it costs \$2,933 per QALY saved; and for patients with type 2 diabetes who do not use insulin, it costs \$3,530 per QALY saved. The cost savings are weighted based on the prevalence of the disease; thus, the savings are greatest when screening is performed for those with type 2 diabetes not using insulin, the largest subgroup of this population with diabetes.

A United Kingdom study compared the cost-effectiveness of conventional versus intensive blood-glucose control in patients with type 2; it found that intensive management increased treatment costs but substantially reduced the costs of complications related to diabetes and increased the time free of complications. Although costs were reduced for the treatment of diabetic retinopathy in the intensive management group, these findings were not statistically significant.

A cost-utility analysis using a computer model of detection and treatment of diabetic retinopathy in patients with type 1 and type 2 diabetes demonstrated that ophthalmic care reduced the prevalence of blindness by 52% and that the direct costs of care were less than the losses in productivity and the costs of facilities provided for disability.

See Appendix 6 in the original guideline document for more information on cost analysis.

METHOD OF GUIDELINE VALIDATION

Internal Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

These guidelines were reviewed by Council and approved by the Board of Trustees of the American Academy of Ophthalmology (September 2008).

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

The ratings of importance to the care process, (A-C) and the ratings for strength of evidence, (I-III) are defined at the end of the "Major Recommendations" field.

Diagnosis

History

- Duration of diabetes (Klein et al., "Prevalence and risk of diabetic retinopathy when age at diagnosis is less than 30 years," 1984; Klein et al., 1988; Davis et al., 1998) [A:I]
- Past glycemic control (hemoglobin A_{1c}) (Klein et al., 1988; Davis et al., 1998; The Diabetes Control and Complications Trial Research Group, 1995) [A:I]
- Medications [A:III]
- Medical history (e.g., obesity, [A:III] renal disease, (Klein et al., "Prevalence and risk of diabetic retinopathy when age at diagnosis is less than 30 years," 1984; Klein et al., "Prevalence and risk of diabetic retinopathy when age at diagnosis is 30 or more years," 1984) [A:II] systemic hypertension, (Klein et al., "Prevalence and risk of diabetic retinopathy when age at diagnosis is less than 30 years," 1984; Klein et al., "Prevalence and risk of diabetic retinopathy when age at diagnosis is 30 or more years," 1984) [A:I] serum lipid levels, (Chew et al., 1996) [A:II] pregnancy (Klein, Moss, & Klein, 1990; Chew et al., 1995) [A:I])
- Ocular history [A:III] (e.g., trauma, ocular injection, surgery, including laser treatment and refractive surgery)

Examination

- Visual acuity (Early Treatment Diabetic Retinopathy Study Research Group, ETDRS report number 9, 1991) [A:I]
- Slit-lamp biomicroscopy [A:III]
- Intraocular pressure [A:III]
- Gonioscopy when indicated [A:III]
- Dilated funduscopy including stereoscopic examination of the posterior pole (Early Treatment Diabetic Retinopathy Study Research Group, 1985) [A:I]
- Examination of the peripheral retina and vitreous [A:III]

A dilated pupil is necessary to ensure optimal examination of the retina, because only 50% of eyes are correctly classified for the presence and severity of retinopathy through undilated pupils (Klein et al., 1985). [A:I] Slit-lamp biomicroscopy with accessory lenses is the recommended method to evaluate retinopathy in the posterior pole and midperipheral retina (Early Treatment Diabetic Retinopathy Study Research Group, 1985). [A:III] The examination of the peripheral retina is best performed with indirect ophthalmoscopy or with slit-lamp biomicroscopy, combined with a contact lens. [A:III]

Examination Schedule

Recommended Eye Examination Schedule for Patients with Diabetes Mellitus

Diabetes Type	Recommended Time of First Examination	Recommended Follow-up*
Type 1	3-5 years after diagnosis (Klein et al., "Prevalence and risk of diabetic retinopathy when age at diagnosis is less than 30 years," 1984) [A:II]	Yearly (Klein et al., "Prevalence and risk of diabetic retinopathy when age at diagnosis is less than 30 years," 1984 [A:II]
Type 2	At time of diagnosis (Klein et al., "Prevalence and risk of diabetic retinopathy when age at diagnosis is 30 or more years," 1984; "The prevalence of retinopathy in impaired glucose tolerance," 2007) [A:II]	Yearly (Klein et al., "Prevalence and risk of diabetic retinopathy when age at diagnosis is 30 or more years," 1984; "The prevalence of retinopathy in impaired glucose tolerance," 2007) [A:II]
Prior to pregnancy (type 1 or type 2)	Prior to conception or early in the first trimester (Klein, Moss, & Klein, 1990; Chew et al., 1995; The Diabetes Control and Complications Trial Research Group, 2000) [A:I]	No retinopathy to mild or moderate nonproliferative diabetic retinopathy (NPDR): every 3-12 months [A:I] Severe NPDR or worse: every 1-3 months [A:I] (Klein, Moss, & Klein., 1990; Chew et al., 1995; The Diabetes Control and Complications Trial Research Group, 2000)

*Abnormal findings may dictate more frequent follow-up examinations.

Treatment

Laser photocoagulation surgery is the standard technique for treating diabetic retinopathy. In general, it is advised for patients with high-risk proliferative diabetic retinopathy, clinically significant macular edema, or neovascularization of the anterior chamber angle (Murphy & Egbert, 1979; The Diabetic Retinopathy Study Research Group, 1987; Early Treatment Diabetic Retinopathy Study Research Group, 1987). [A:I] Detailed management recommendations for patients with diabetes are summarized in the table below and are described in the main text of the original guideline document.

Table: Management Recommendations for Patients with Diabetes

Severity of Retinopathy	Presence of Clinically Significant Macular Edema (CSME¹)	Follow-up (Months)	Panretinal Photocoagulation (Scatter) Laser	Fluorescein Angiography	Focal and/or Grid Laser²
1. Normal or minimal non-proliferative diabetic retinopathy (NPDR)	No	12	No	No	No
2. Mild to moderate NPDR	No	6-12	No	No	No
	Yes	2-4	No	Usually	Usually ^{1,3}
3. Severe NPDR	No	2-4	Sometimes ⁴	Rarely	No
	Yes	2-4	Sometimes ⁴	Usually	Usually ⁵
4. Non-high-risk proliferative diabetic retinopathy (PDR)	No	2-4	Sometimes ⁴	Rarely	No
	Yes	2-4	Sometimes ⁴	Usually	Usually ³
5. High-risk PDR	No	2-4	Usually	Rarely	No
	Yes	2-4	Usually	Usually	Usually ⁵
6. Inactive/involved PDR	No	6-12	No	No	Usually
	Yes	2-4	No	Usually	Usually

¹Exceptions include: hypertension or fluid retention associated with heart failure, renal failure, pregnancy, or any other causes that may aggravate macular edema. Deferral of photocoagulation for a brief period of medical treatment may be considered in these cases. Also, deferral of CSME treatment is an option when the center of the macula is not involved, visual acuity is excellent, close follow-up is possible, and the patient understands the risks.

²Adjunctive treatments that may be considered include intravitreal corticosteroids or anti-vascular endothelial growth factor agents (off-label use).

³Deferring focal photocoagulation for CSME is an option when the center of the macula is not involved, visual acuity is excellent, close follow-up is possible, and the patient understands the risks. However, initiation of treatment with focal photocoagulation should also be considered because, although treatment with focal photocoagulation is less likely to improve the vision, it is more likely to stabilize the current visual acuity. Treatment of lesions close to the foveal avascular zone may result in damage

to central vision and with time, such laser scars may expand and cause further vision deterioration. Closer follow-up may be necessary for macular edema that is not clinically significant.

⁴Panretinal photocoagulation surgery may be considered as patients approach high-risk PDR. The benefit of early panretinal photocoagulation at the severe nonproliferative or worse stage of retinopathy is greater in patients with type 2 diabetes than in those with type 1. Treatment should be considered for patients with severe NPDR and type 2 diabetes. Other factors, such as poor compliance with follow-up, impending cataract extraction or pregnancy, and status of the fellow eye will help in determining the timing of the panretinal photocoagulation.

⁵It is preferable to perform focal photocoagulation first, prior to panretinal photocoagulation, to minimize panretinal photocoagulation laser-induced exacerbation of the macular edema.

Follow-Up

History

- Symptoms [A:III]
- Systemic status (pregnancy, blood pressure, serum cholesterol, renal status) [A:III]
- Glycemic status (hemoglobin A_{1c}) (Klein et al., 1988; Davis et al., 1998; The Diabetes Control and Complications Trial Research Group, 1995) [A:I]

Examination

A follow-up examination should include the following elements:

- Visual acuity (Early Treatment Diabetic Retinopathy Study Research Group, ETDRS report number 9, 1991) [A:I]
- Slit-lamp biomicroscopy with iris examination (Jacobson, Murphy, & Rosenthal, 1979) [A:II]
- Intraocular pressure [A:III]
- Gonioscopy (if iris neovascularization is suspected or present or if intraocular pressure is increased) (Jacobson, Murphy, & Rosenthal, 1979) [A:II]
- Stereoscopic examination of the posterior pole after dilation of the pupils (Early Treatment Diabetic Retinopathy Study Research Group, 1985) [A:I]
- Peripheral retina and vitreous examination, when indicated (Early Treatment Diabetic Retinopathy Study Research Group, ETDRS report number 12, 1991) [A:II]

Recommended intervals for follow-up are given in the above table.

Provider

Because of the complexities of the diagnosis and surgery for proliferative diabetic retinopathy, the ophthalmologist caring for patients with this condition should be familiar with the specific recommendations of the Diabetic Retinopathy Study, Early Treatment Diabetic Retinopathy Study, the United Kingdom Prospective Diabetes Study, Diabetes Control and Complications Trial, and the Epidemiology of Diabetes Interventions and Complications. [A:III] The ophthalmologist should also have training in and experience with the management of this particular condition. [A:III]

Counseling/Referral

The ophthalmologist should refer patients with diabetes who do not have a primary care physician for appropriate management of their systemic condition. [A:III] The ophthalmologist should communicate examination results to the physician who is managing ongoing diabetes care. [A:III]

Those whose conditions fail to respond to surgery and those for whom further treatment is unavailable should be provided with proper professional support and offered referral for counseling, vision rehabilitation, or social services as appropriate (American Academy of Ophthalmology Vision Rehabilitation Committee, 2007). [A:III] Vision rehabilitation restores functional ability (Stelmack et al., 2008) [A:I] and patients with functionally limiting postoperative visual impairment should be referred for vision rehabilitation and social services (American Academy of Ophthalmology Vision Rehabilitation Committee, 2007). [A:III] More information on vision rehabilitation, including materials for patients, is available at <http://www.aao.org/smartsight>.

Definitions:

Ratings of Importance to Care Process

Level A, defined as most important

Level B, defined as moderately important

Level C, defined as relevant but not critical

Ratings of Strength of Evidence

Level I includes evidence obtained from at least one properly conducted, well-designed randomized, controlled trial. It could include meta-analyses of randomized controlled trials.

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- Descriptive studies
- Case reports
- Reports of expert committees/organization (e.g., Preferred Practice Patterns [PPP] panel consensus with external peer review)

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

REFERENCES SUPPORTING THE RECOMMENDATIONS

[References open in a new window](#)

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is identified and graded for most recommendations (see "Major Recommendations" field).

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Effective evaluation and management of diabetic retinopathy resulting in prevention, retardation, or reversal of visual loss and improved vision-related quality of life

POTENTIAL HARMS

- An ophthalmologist who orders fluorescein angiography must be aware of the potential risks associated with the procedure; severe medical complications may occur, including death (about 1/200,000 patients). Each angiography facility should have in place a care plan or emergency plan and a clear protocol to minimize the risks and to manage any complications. Although detrimental effects of fluorescein dye on the fetus have not been documented, fluorescein dye does cross the placenta into the fetal circulation.
- Side effects and complications associated with focal laser photocoagulation for diabetic macular edema:
 - Initial decrease in central vision
 - Paracentral scotomas if laser burns have been placed close to the fovea, especially large or confluent burns
 - Permanent central scotoma from inadvertent foveal burns
 - Subretinal fibrosis with choroidal neovascularization (rarely)
- Side effects and complications associated with panretinal photocoagulation (scatter) for severe nonproliferative diabetic retinopathy or proliferative diabetic retinopathy:
 - Central vision loss from macular edema
 - Peripheral visual field constrictions with poor dark adaptation
 - Vitreous hemorrhage if neovascularization is present
 - Loss of accommodation

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

- **Preferred Practice Patterns provide guidance for the pattern of practice, not for the care of a particular individual.** While they should generally meet the needs of most patients, they cannot possibly best meet

the needs of all patients. Adherence to these Preferred Practice Patterns will not ensure a successful outcome in every situation. These practice patterns should not be deemed inclusive of all proper methods of care or exclusive of other methods of care reasonably directed at obtaining the best results. It may be necessary to approach different patients' needs in different ways. The physician must make the ultimate judgment about the propriety of the care of a particular patient in light of all of the circumstances presented by that patient. The American Academy of Ophthalmology is available to assist members in resolving ethical dilemmas that arise in the course of ophthalmic practice.

- **Preferred Practice Pattern guidelines are not medical standards to be adhered to in all individual situations.** The Academy specifically disclaims any and all liability for injury or other damages of any kind, from negligence or otherwise, for any and all claims that may arise out of the use of any recommendations or other information contained herein.
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IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

IMPLEMENTATION TOOLS

Personal Digital Assistant (PDA) Downloads
Quick Reference Guides/Physician Guides

For information about [availability](#), see the "Availability of Companion Documents" and "Patient Resources" fields below.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Living with Illness
Staying Healthy

IOM DOMAIN

Effectiveness
Patient-centeredness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

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ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

1998 Sep (revised 2008 Sep)

GUIDELINE DEVELOPER(S)

American Academy of Ophthalmology - Medical Specialty Society

SOURCE(S) OF FUNDING

American Academy of Ophthalmology without commercial support

GUIDELINE COMMITTEE

Retina/Vitreous Panel; Preferred Practice Patterns Committee

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

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FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

These panel and committee members have disclosed the following financial relationships occurring from January 2007 to October 2008:

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IRIDEX – Consultant/Advisor, Equity owner, Patents/Royalty

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Ingrid U. Scott, MD, MPH: Eyetech, Inc. – Consultant/Advisor, Lecture fees; Genentech, Inc. – Consultant/Advisor, Lecture fees; Pfizer Ophthalmics – Consultant/Advisor, Lecture fees

GUIDELINE STATUS

This is the current release of the guideline.

This guideline updates a previous version: American Academy of Ophthalmology Retina Panel, Preferred Practice Patterns Committee. Diabetic retinopathy. San Francisco (CA): American Academy of Ophthalmology (AAO); 2003. 33 p.

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GUIDELINE AVAILABILITY

Electronic copies: Available from the [American Academy of Ophthalmology \(AAO\) Web site](#).

Print copies: Available from American Academy of Ophthalmology, P.O. Box 7424, San Francisco, CA 94120-7424; Phone: (415) 561-8540.

AVAILABILITY OF COMPANION DOCUMENTS

The following is available:

- Summary benchmarks for preferred practice patterns. San Francisco (CA): American Academy of Ophthalmology; 2008 Nov. 22 p.

Electronic copies: Available in Portable Document Format (PDF) or Personal Digital Assistant (PDA) format from the [American Academy of Ophthalmology \(AAO\) Web site](#).

Print copies: Available from American Academy of Ophthalmology, P.O. Box 7424, San Francisco, CA 94120-7424; Phone: (415) 561-8540.

PATIENT RESOURCES

None available

NGC STATUS

This summary was completed by ECRI on February 20, 1999. The information was verified by the guideline developer on April 23, 1999. This summary was updated again on April 30, 2004. The information was verified by the guideline developer May 20, 2004. This NGC summary was updated by ECRI Institute on April 22, 2009. The updated information was verified by the guideline developer on May 15, 2009.

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